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| APPLICATION NO.                               | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO |
|---|-----------------|----------------------|------------------------|-----------------|
| 10/075,355                                    | 02/14/2002      | Hildegard M. Kramer  | 5190                   | 8887            |
| 7   | 7590 03/26/2004 |                      | EXAM                   | INER            |
| GENZYME CORPORATION                           |                 |                      | WOITACH, JOSEPH T      |                 |
| 15 PLEASANT STREET CONNECTOR<br>P.O. BOX 9322 |                 |                      | ART UNIT               | PAPER NUMBER    |
| FRAMINGHAM, MA 01701-9322                     |                 |                      | 1632                   |                 |
|   |                 |                      | DATE MAILED: 03/26/200 | 4               |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)   |  |
|---|--|--|--|
| Office Action Comment   | 10/075,355   | KRAMER ET AL.  |  |
| Office Action Summary   | Examiner   | Art Unit   |  |
|   | Joseph T. Woitach  | 1632   |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c   | orrespondence address  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period where the reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  | 86(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) day rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S C. § 133). |  |
| Status  |  |  |  |
| <ul> <li>1) ☐ Responsive to communication(s) filed on 14 Fe</li> <li>2a) ☐ This action is FINAL. 2b) ☐ This</li> <li>3) ☐ Since this application is in condition for allowar closed in accordance with the practice under E</li> </ul>  | action is non-final.<br>ace except for formal matters, pro   |  |  |
| Disposition of Claims   | ,  |  |  |
| 4) ☐ Claim(s) 1-54 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-54 are subject to restriction and/or example and the subjection Papers   | vn from consideration.   |  |  |
| ··· <u> </u>  |  |  |  |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the orange Replacement drawing sheet(s) including the correction of the orange and the correction of the orange replacement drawing sheet acceptance of the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the correction of the orange replacement drawing sheet (s) including the orange | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj  | e 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).  |  |
| Priority under 35 U.S.C. § 119  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents</li> <li>2. Certified copies of the priority documents</li> <li>3. Copies of the certified copies of the prior application from the International Bureau</li> <li>* See the attached detailed Office action for a list of the certified copies of the certified copies</li> </ul>  | s have been received.<br>s have been received in Application<br>ity documents have been received<br>(PCT Rule 17.2(a)).  | on No ed in this National Stage  |  |
| Attachment(s)   |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:   |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 15, 16, drawn to a method of making a biocompatible fleece comprising providing solution of a macromer that is hydrophilic, biodegradable and a cross-linking moiety; freezing the solution into the desired shape and cross-linking into a fleece/matrix, classified in class 530, subclass 333.
- II. Claims 14, 17-20, 22, 24-36, 48, 49 and 50, drawn to a biocompatible fleece, classified in class 530, subclass 402.
- III. Claims 21, 23 and 50, drawn to a biocompatible fleece comprising cells, classified in class 435, subclass 325.
- IV. Claims 37-37, 52 and 53, drawn to a method of treatment of a wound or defect by applying a slurry of fleece particles, classified in class 530, subclass 333.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful by itself as a slurry (as set forth in claim 37) or as a substrate for a variety of other uses and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the

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species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the general methods of treatment can be accomplished with different matrices or the same matrices made by different means. Further, the product can be used in non-treatment methods, such as providing a substrate to culture cells. With respect to group II only claim 47 recites the delivery of a cell, and this can be accomplished as set forth above, with other matrices.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for each group is not co-extensive with the remaining groups, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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